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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,173	08/23/2001	Henry M. Israel	1093NES-US	1648

7590 06/29/2004

Dekel Patent Ltd.
Beit HaRofim
Room 27
18 Menuha VeNahala Street
Rehovot,
ISRAEL

EXAMINER	
THALER, MICHAEL H	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,173	ISRACL, HENRY M.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 13, 2004 has been entered.

Claims 1, 2, 4-10 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yachia et al. (5,246,445). Yachia et al., in figure 2b, disclose a stent assembly inherently capable for use in a blood vessel comprising an upstream portion (the top portion of the stent shown in figure 2b) having a constricting portion (the top portion of the stent which converges as one follows it in the top to bottom direction) inherently adapted to modify a flow characteristic of embolic material disposed in the blood stream (This portion is inherently capable of modifying a flow characteristic of embolic material disposed in the blood stream since, like the convergence 24 of applicant's invention, it converges along the flow path of the stent, reducing the cross-sectional area of the lumen.) and a downstream portion (the large bulge near the

middle and lower portion of the stent) inherently comprising a trapping region for trapping embolic material (This portion is inherently capable of trapping embolic material since, like the trapping region 22 of applicant's invention, it diverges along the flow path of the stent to allow the embolic material to remain in the divergent region or bulge), the trapping region being asymmetric about a plane which is perpendicular to the longitudinal axis of the stent and located at the point of the largest diameter of the stent (since the shape of the portion of the trapping region on one side of this plane is not a mirror image of the shape of the portion of the trapping region on the other side of this plane). Alternatively, it would have been obvious that the downstream portion (the large bulge near the middle and lower portion of the stent) comprises a trapping region for trapping embolic material since it is enlarged in diameter.

Alternatively, Yachia et al., in figure 1b, disclose a stent assembly for use in a blood vessel (col. 2, lines 65-67) comprising an upstream portion (for example, the converging, right portion of the left bulge 2 shown in figure 1b) inherently adapted to modify a flow characteristic of embolic material disposed in the blood stream (This portion inherently modifies a flow characteristic of embolic material disposed in the blood

stream since, like the convergence 24 of applicant's invention, it converges along the flow path of the stent, reducing the cross-sectional area of the lumen.) and a downstream portion (for example, the right bulge 2 shown in figure 1b) inherently comprising a trapping region for trapping embolic material (This portion inherently traps embolic material since, like the trapping region 22 of applicant's invention, it diverges along the flow path of the stent to allow the embolic material to remain in the divergent region or bulge. Alternatively, it would have been obvious that the Yachia et al. stent assembly performs these functions for the reasons set forth above. As to the term "asymmetric" in claim 1, line 6, the claim is broad in that it does not define what line or plane the trapping region is asymmetric relative to. For example, the trapping region could be asymmetric relative to a plane oriented at 45 degrees relative to the longitudinal axis of the stent and still meet the terms of the claim, noting the phrase "non-zero angle" in claim 21. The trapping region in figure 1b of Yachia et al. is asymmetric relative to a plane oriented at 45 degrees relative to the longitudinal axis of the stent since the shape of the portion of the trapping region on one side of this plane is not a mirror image of the shape of the portion of the trapping region on the other side of this plane. As to claim 2, the

upstream portion may be considered to be the right portion of the left bulge 2 as well as the narrow portion between bulges 2 as shown in figure 1b.

Claims 3 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yachia et al. (5,246,445). As to claims 3 and 19, Yachia et al. fail to disclose a space between the downstream portion and the upstream portion to allow blood to flow therethrough into a side branch of the blood vessel. However, it is well known in this art to provide stents with spaces or openings to allow to allow blood to flow therethrough into a side branch of the blood vessel. It would have been obvious to provide such an opening or space in the Yachia et al. stent so that it too would have this advantage. In any event, Yachia et al. discloses spacing the upstream portion from the downstream portion in col. 4, lines 59-61. As to claim 14, Yachia et al. fail to disclose a restrictor element. However, it is well known in this art to provide restrictor elements to stents so that the expansion of the stent is precisely and automatically limited. It would have been obvious to include a restrictor element in the Yachia et al. stent so that it too would have this advantage. As to claims 15-18, Yachia et al. fail to disclose anti-thrombogenic or friction enhancing and reducing agents. However, it is well known in this art to

provide stents with these agents 1) so that they are biocompatible, 2) so that they can be positively secured to blood vessels and 3) to reduce trauma on the blood. It would have been obvious to include these agents on the Yachia et al. stent so that it too would have these advantages. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

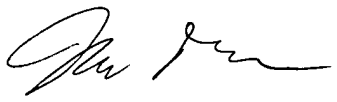
Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yachia et al. (5,246,445) in view of Rosenbluth (4,893,623). Yachia et al. fail to disclose the trapping region (in figure 2b) being asymmetric about its longitudinal axis. However, Rosenbluth teaches that the cross-section of a stent within the prostate should be shaped as shown in figure 7 in order to approximate the cross-sectional shape of the native prostatic urethra (col. 11, lines 50-56). It would have been obvious to so shape the figure 2b stent of Yachia et al. so that it too would have this advantage. The stent in figure 7 of Rosenbluth is asymmetric about its longitudinal axis.

Applicant's arguments filed May 13, 2004 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.



mht
6/24/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731